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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,763	01/09/2006	Yasumasa Hamada	126577	3400

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EXAMINER	
SACKEY, EBENEZER O	

ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,763	HAMADA ET AL.	
	Examiner	Art Unit	
	EBENEZER SACKEY	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/29/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-13 are pending.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Information Disclosure Statement

Receipt of the Information Disclosure Statement filed on 03/29/06 is acknowledged and has been entered into the file. Assigned copy of the 1449 is attached herewith.

Claim Objections

In claim 1, asymmetric has been incorrectly spelled. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The numerous brackets in the claim render the claim indefinite since it is not clear what is inclusive and subject matter taken out of the claim. Correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 8-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1- of copending

Application No. 11/795,035 ('305'). Although the conflicting claims are not identical, they are not patentably distinct from each other because there is considerable amount of overlap between the process of the current invention and that of '035'. Note the current process provides for the preparation of optically active β-hydroxy-α-aminocarboxylic acid of formulae (2) or (3), which is similar and inclusive of the reagents and catalysts employed in the process of '035'. Hence, the use of reagents and catalyst which has been known to be useful for the preparation of β-hydroxy-α-aminocarboxylic acid of formulae (2) or (3) is *prima facie* obvious absent a showing of unexpected properties. The motivation being the desire to prepare β-hydroxy-α-aminocarboxylic acid of formulae (2) or (3) as claimed herein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by JP-A 02-172956.

Applicants claim a process for making optically active β-hydroxy-α-aminocarboxylic acid of formulae (2) or (3), comprising subjecting α-aminoacyl acetic acid ester of formula (I) to hydrogenation by catalytic asymmetric hydrogenation in the presence of an acid.

JP-'956' disclose the preparation of β-hydroxy-α-aminocarboxylic acid of formulae (2) or (3), comprising subjecting α-aminoacyl acetic acid ester of formula (I) to hydrogenation by catalytic asymmetric hydrogenation in the presence of an acid. See page 1 of 2, especially page 381.

Claim Rejections - 35 U.S.C. § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP A 02-172956 in view of Noyori et al., and JP- 06-080617 Cited by applicants.

Applicants claim a process for making optically active β-hydroxy-α-aminocarboxylic acid of formulae (2) or (3), comprising subjecting α-aminoacyl acetic acid ester of formula (I) to hydrogenation by catalytic asymmetric hydrogenation in the presence of an acid.

Determination of the scope and content of the prior art (MPEP §2141.01)

JP-'956' teach the preparation of β-hydroxy-α-aminocarboxylic acid of formulae (2) or (3), comprising subjecting α-aminoacyl acetic acid ester of formula (I) to hydrogenation by catalytic asymmetric hydrogenation in the presence of an acid. See the entire reference especially page 381.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

JP-'956' differs from the current process in that the use of Group VIII metal complex with phosphine ligand is not required. However, Noyori et al., and JP-'617' all teach that the use of metal ligand complex in hydrogenation is known. Note the ligand of claim 4 is shown on page 1 of '617'. Additionally, Noyori et al., also teach that hydrogenation catalyst complexes such as $RuX^2(R^2\text{-BINAP})$ (claims 5-8) are also known and with a reasonable expectation of success can be employed in hydrogenation process. See pages 59-65.

Finding of prima facie obviousness---rational and motivation (MPEP §2142-2143)

Accordingly, at the time of filing this application, it would have been *prima facie* obvious to one of ordinary skill in the art to prepare β-hydroxy-α-aminocarboxylic acid of formulae (2) or (3), from the specified reagents and guided by the knowledge in the art that catalysts such as Group VIII metal ligand complex are used for hydrogenation and with a reasonable expectation that the resulting products would be pure because Noyori et al., and "956' and '617' teaches the use of the catalyst in the instant process. Hence, one in possession of '956', guided by the knowledge in the art is in possession of the instant process absent a showing of unexpected results or properties. The process that is being claimed is a predictable and expected process. Thus, the use of an asymmetric catalysts in the instant process is *prima facie* obvious.

Accordingly, the instantly claimed process would have been suggested to one of ordinary skill in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EBENEZER SACKEY whose telephone number is (571)272-0704. The examiner can normally be reached on 7.30-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E.O.S./
Patent Examiner, AU 1624

/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624